

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference UPN-P3230PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2004/028817	International filing date (day/month/year) 30/09/2004	(Earliest) Priority Date (day/month/year) 30/09/2003
Applicant THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 10 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☒ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☒ none of the figures is to be published with the abstract.

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☒ in written format
- ☒ in computer readable form
- c. time of filing/furnishing
- ☒ contained in the international application as filed
- ☒ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purpose of search
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

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Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Sequences of adeno-associated virus capsids and vectors and host cells containing these sequences are provided. Also described are methods of using such host cells and vectors in production of rAAV particles. AAV-mediated delivery of therapeutic and immunogenic genes using the vectors of the invention is also provided.

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 45 comprises a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

1-4(partially), 5-7(completely), 28-29(partially), 30-45(completely)
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4 (partially),5-7 (completely)

Subject-matter relating to AAV clade E.

2. claims: 1-4 (partially),10,11 (completely)

Subject-matter relating to AAV clade D.

3. claims: 1-4 (partially),14,15 (completely)

Subject-matter relating to AAV clade B.

4. claims: 1-4 (partially),18,19 (completely)

Subject-matter relating to AAV clade A.

5. claims: 1-4 (partially),22,23 (completely)

Subject-matter relating to AAV clade C.

6. claims: 1-4 (partially),26,27 (completely)

Subject-matter relating to AAV clade F.

7. claims: 1-4 (partially)

Subject-matter relating to AAV clades not covered by inventions 1-6.

Inventions 8-34: Claims 8,9,46-58 (all partially)

Subject-matter relating to the AAVs as defined in claim 9, i.e. 30.10/pi.1 or 30.12/pi.2 or 30.19.pi.3 or hu.66 or modified rh.2 or hu.67, respectively.

Invention 35-41: Claims 12,13,46-58 (all partially)

Subject-matter relating to the AAVs as defined in claim 13, i.e. 2-15/rh.62 or 1-7/rh.48 or 4-9/rh.54 or 4-19/rh.55 or modified cy.5 or modified rh.13 or modified rh.37, respectively.

Inventions 42-64: Claims 16,17,46-58 (all partially)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Subject-matter relating to the AAVs as defined in claim 16,
i.e. 52/hu.19 or 52.1/hu.20 or 54.5/hu.23 or
140.1/hu.51 or 140.2/hu.52, respectively.

Inventions 65-69: Claims 20,21,46-58 (all partially)

Subject-matter relating to the AAVs as defined in claim 21,
i.e. 128.1/hu.43 or 128.3/hu.44 or hu.46 or modified hu.46
or 130.4/hu.48, respectively.

Inventions 70-85: Claims 24,25,46-58 (all partially)

Subject-matter relating to the AAVs as defined in claim 25,
i.e. 3.1/hu.9 or 16.8/hu.10 or 16.12/hu.11 or H-1/hu.1
or hu.18 or 161.6/hu.61, respectively.

Invention 86: Claims 28 and 29 (partially), 30-45 (all completely)

Subject-matter relating to hu.14/AAV9.

Inventions 87-88: Claims 28,29,46-58 (all partially)

Subject-matter relating to the AAVs hu.31 or hu.32,
respectively.

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12N15/864 A61K48/00 C07K14/015		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12N C07K A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE, CHEM ABS Data, EMBL		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 310 571 A (TRUSTEES OF THE UNIVERSITY OF) 14 May 2003 (2003-05-14) figure 2 page 3, line 6 - line 19 paragraphs '0075!', '0077!', '0079! paragraph '0126! paragraphs '0132! - '0138! paragraphs '0176! - '0183! tables 8,9 & US 2003/138772 A1 (ALVIRA MAURICIO R ET AL) 24 July 2003 (2003-07-24) cited in the application <div style="text-align: center;">----- -/--</div>	1-7
<div style="display: flex; justify-content: space-between;"> <input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex. </div>		
<div style="display: flex;"> <div style="flex: 1;"> <p>* Special categories of cited documents:</p> <p>*A* document defining the general state of the art which is not considered to be of particular relevance</p> <p>*E* earlier document but published on or after the international filing date</p> <p>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>*O* document referring to an oral disclosure, use, exhibition or other means</p> <p>*P* document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="flex: 1;"> <p>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>*G* document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search <div style="text-align: center;">22 March 2005</div>		Date of mailing of the international search report <div style="text-align: center;">18.05.2005</div>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer <div style="text-align: center;">Mandl, B</div>

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GAO GUANGPING ET AL: "Adeno-associated viruses undergo substantial evolution in primates during natural infections" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 100, no. 10, 13 May 2003 (2003-05-13), pages 6081-6086, XP002255703 ISSN: 0027-8424 the whole document -----	1-7
A	GAO G-P ET AL: "Novel adeno-associated viruses from rhesus monkeys as vectors for human gene therapy" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE, vol. 99, no. 18, 3 September 2002 (2002-09-03), pages 11854-11859, XP002229849 ISSN: 0027-8424 cited in the application the whole document -----	1-7
A	GRIMM D ET AL: "FROM VIRUS EVOLUTION TO VECTOR REVOLUTION: USE OF NATURALLY OCCURRING SEROTYPES OF ADENO-ASSOCIATED VIRUS (AAV) AS NOVEL VECTORS FOR HUMAN GENE THERAPY" CURRENT GENE THERAPY, vol. 3, no. 4, August 2003 (2003-08), pages 281-304, XP009040225 ISSN: 1566-5232 figure 3 -----	1-7
A	RUTLEDGE E A ET AL: "INFECTIOUS CLONES AND VECTORS DERIVED FROM ADENO-ASSOCIATED VIRUS (AAV) SEROTYPES OTHER THAN AAV TYPE 2" JOURNAL OF VIROLOGY, vol. 72, January 1998 (1998-01), pages 309-319, XP002924102 ISSN: 0022-538X the whole document -----	1-7
A	RABINOWITZ JOSEPH E ET AL: "Cross-packaging of a single adeno-associated virus (AAV) type 2 vector genome into multiple AAV serotypes enables transduction with broad specificity" JOURNAL OF VIROLOGY, vol. 76, no. 2, January 2002 (2002-01), pages 791-801, XP002247245 ISSN: 0022-538X the whole document -----	1-7
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/052052 A (TRUSTEES OF THE UNIVERSITY OF ; GAO GUANGPING (US); ALVIRA MAURICIO (U) 26 June 2003 (2003-06-26) the whole document -----	28-45
P,X	GAO GUANGPING ET AL: "Clades of adeno-associated viruses are widely disseminated in human tissues" JOURNAL OF VIROLOGY, vol. 78, no. 12, June 2004 (2004-06), pages 6381-6388, XP002321999 ISSN: 0022-538X the whole document -----	28-45

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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1310571	A	14-05-2003	CA 2406745 A1	13-05-2003
			CA 2465868 A1	22-05-2003
			EP 1310571 A2	14-05-2003
			EP 1456419 A2	15-09-2004
			JP 2003235562 A	26-08-2003
			WO 03042397 A2	22-05-2003
			US 2003138772 A1	24-07-2003
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			CA 2465868 A1	22-05-2003
			EP 1310571 A2	14-05-2003
			EP 1456419 A2	15-09-2004
			JP 2003235562 A	26-08-2003
			WO 03042397 A2	22-05-2003
WO 03052052	A	26-06-2003	AU 2002359284 A1	30-06-2003
			CA 2469053 A1	26-06-2003
			EP 1463805 A2	06-10-2004
			WO 03052052 A2	26-06-2003
			US 2005014262 A1	20-01-2005
			US 6837318 B1	04-01-2005